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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,874	04/19/2005	Ryuji Ueno	Q87423	5640

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
POLANSKY, GREGG	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
11/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@SUGHRUE.COM
PPROCESSING@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/531,874	UENO, RYUJI	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 18-25* is/are pending in the application.

4a) Of the above claim(s) *3,4,6,8,10 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,9,11-13 and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's response, filed 7/02/2009, to the Office Action mailed 3/02/2009 is acknowledged. Applicant has amended Claims 1, 18, 20, and 21, added Claims 22-25, and presented arguments in response to the Office Action.

2. Claims 1, 3-13, and 18-25 are pending.

3. Claims 1, 5, 7, 9, 11-13, and 19-25 are presently under consideration.

4. Applicant's arguments have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 5, 7, 9, 11-13, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno et al. (U.S. Patent No. 5,234,954), in view of Dietz (Pediatrics, Vol. 101, Issue 3 (Supplement), pages 518-525).

Ueno et al. teach a method for the treatment of hyperlipidemia comprising administration of a 15-keto-prostaglandin compound, including 13,14-dihydro-15-keto-16-mono or dihalo-prostaglandins, and more specifically, 13,14-dihydro-15-keto-16,16-difluoro-prostaglandin E compounds. See Abstract; column 15, "FORMULATION EXAMPLE 2"; column 20, claim 6; and column 22, claim 10. Ueno et al. teach both the PGE_1 and PGE_2 forms of the 15-keto prostaglandin compounds are useful in the disclosed methods. See last paragraph bridging columns 3-4. Ueno et al. teach the disclosed PGE compounds decrease blood levels of triglyceride, cholesterol or phospholipid (irrespective of cause, e.g., disease, drug or food) by promoting release into the intestine or release with feces. Further, Ueno et al. teach the method useful for reducing said blood lipids in obese individuals. See column 15, lines 27-45. The reference teaches the PGE compounds may be administered systemically by known methods of administration and "the dosage will vary depending on the particular animal or human patient, age, body weight, symptom to be treated, desired therapeutic effect, administration route, term of treatment and the like, [and] satisfactory effects will be obtained with the dosage of 0.001-500 mg/kg administered in 2 to 4 divided doses a day or as a sustained form". See column 14, lines 20-31. With respect to claimed dosage ranges of the active agents in the instant methods, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(11).

Instant Claims 11 and 25 are drawn to 13,14-dihydro-15-keto-16,16-difluoro-PGE_1. As discussed above, Ueno et al. teach 15-keto-prostaglandin compounds, including 13,14-dihydro-15-keto-16-mono or dihalo-prostaglandins, and more specifically, 13,14-dihydro-15-keto-16,16-difluoro-prostaglandin E compounds. Further, Ueno et al. teach PGE_1 and PGE_2 forms of these compounds are useful in the disclosed methods. Ueno et al. disclose the compound 13,14-dihydro-15-keto-16-difluoro-PGE_2. The only difference between this compound and the instantly claimed 13,14-dihydro-15-keto-16,16-difluoro-PGE_1 is the presence of a double bond or a single bond between positions 5 and 6, respectively. Since both forms are encompassed by the disclosure of Ueno et al., it would have been obvious to substitute one for the other to evaluate any differences in pharmacological activity between the two.

Hyperlipidemia is common in obese individuals. See Dietz, page 518 "Abstract" and page 521, "Hyperlipidemia". It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Ueno et al. to treat hyperlipidemia in obese individuals, by the administration of a 15-keto-prostaglandin compound, including a 13,14-dihydro-15-keto-16,16-difluoro-prostaglandin E compound. One would have been motivated to do so by the teaching of Ueno et al. (i.e., Ueno et al. explicitly teach treatment of hyperlipidemia associated with obesity (*supra*)), with further motivation provided by Dietz (i.e., hyperlipidemia association with obesity).

Treating hyperlipidemia in obese individuals (with the same PGE compounds at the same doses as instantly claimed), as closed by Ueno et al., would naturally produce

the same reduction of body weight as is instantly claimed. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicant to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Also see *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant argues "the cited art does not disclose or suggest administering the recited compound to a subject with a recognized need to reduce body weight and for the purpose of reducing the body weight of that subject. Rather, the cited art is simply directed to treating hyperlipidemia. Applicant submits that hyperlipidemia is a disease diagnosed by higher serum lipid and is not necessarily associated with obesity."

The Examiner respectfully disagrees. The prior art teaches hyperlipidemia is common in obese individuals. As discussed above, one of skill in the art would have been motivated by the teachings of both references to treat hyperlipidemia associated with obesity. There is no need for recognition by the cited prior art of a need to reduce body weight since the artisan's suggested motivation to use the methods disclosed by the art is the desire to treat hyperlipidemia associated with obesity. Further, Applicant has acknowledged that "obese subjects are in need of a reduction of body weight." See the 1st full paragraph on page 14 of Applicant's Remarks, filed 7/02/2009.

Applicant state an independent claim reciting a method of treating obesity in a mammalian subject which comprises administering to a mammalian subject in need of treatment for obesity an effective amount of 13,14-dihydro-15-keto-16,16-difluoro-PGE_1, has been added to the pending claims; therefore, Applicant argues "since the cited art does not specifically teach or suggest that compound" the claim is not obvious over the cited art.

Applicant's argument is not convincing. As discussed above, Ueno et al. teach 15-keto-prostaglandin compounds, including 13,14-dihydro-15-keto-16-mono or dihalo-prostaglandins, and more specifically, 13,14-dihydro-15-keto-16,16-difluoro-prostaglandin E compounds. Further, Ueno et al. teach PGE_1 and PGE_2 forms of these compounds are useful in the disclosed methods. Ueno et al. disclose the compound 13,14-dihydro-15-keto-16-difluoro-PGE_2. The only difference between this compound and the instantly claimed 13,14-dihydro-15-keto-16,16-difluoro-PGE_1 is the presence of a double bond or a single bond between positions 5 and 6, respectively. Since both forms are encompassed by the disclosure of Ueno et al., it would have been obvious to substitute one for the other to evaluate any differences in pharmacological activity between the two.

Conclusion

7. Claims 1, 5, 7, 9, 11-13, and 19-25 are rejected.

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614